

AVIATION RULEMAKING ADVISORY COMMITTEE

Repair Station Quality Assurance Technical Report

A report on the advantages and disadvantages of requiring a quality assurance system in part 145 of Title 14, Code of Federal Regulations

March 2002

Attachment 6

INTRODUCTION

The Federal Aviation Administration (FAA) issued notice No. 99-09, Part 145 Review: Repair Stations; Notice of Proposed Rulemaking (64 FR 33142, June 21, 1999), proposing to update and revise part 145 of Title 14, Code of Federal Regulations. The FAA proposed that each repair station establish a quality assurance system acceptable to the Administrator. The FAA stated that guidance on establishing an effective quality assurance system would be included in advisory material published concurrently with the final rule if adopted. The FAA noted that an acceptable quality assurance system would be based on the repair station's size and type of operations. However, commenters generally opposed adding a quality assurance requirement to part 145, citing various concerns addressed later in this report. In amendment No. 145-27, Repair Stations; Final Rule With Request for Comments and Direct Final Rule With Request for Comments (66 FR 41088, August 6, 2001), the FAA removed its proposal for a quality assurance requirement and stated that it intends to address this issue in a subsequent rulemaking. The FAA assigned the Aviation Rulemaking Advisory Committee, Air Carrier and General Aviation Maintenance Issues area (the committee) with the task of producing a technical report that reviews current regulatory requirements for a quality assurance system and recommends a preferred quality assurance system (66 FR 53281, October 19, 2001).

In this technical report, "quality assurance system" refers to a program that monitors the controls used to ensure quality in manufacturing a product or offering a service. Quality control comprises the actual mechanisms an organization uses to ensure quality, such as training procedures, inspections, and procedures manuals. A quality assurance system monitors these quality control mechanisms to verify they are being used and are effective. At present, part 145 incorporates quality control under §145.211 but contains no requirements for quality assurance. Numerous industry commenters and members of the committee note that most repair stations already have quality assurance programs.

CURRENT QUALITY ASSURANCE PROGRAM

[Should describe that there is not one. To be added.]

CONCERNS WITH REGULATING QUALITY ASSURANCE

The committee members agree that a quality assurance program is nearly a necessity for a repair station in the current aviation marketplace. Many committee members also acknowledge the value of having some regulatory controls in place to encourage repair stations to engage in quality control. Some committee members suggest that the FAA implement a voluntary quality assurance program. However, the committee is decidedly split on whether a quality assurance system should be required under part 145.

The committee members differ on the effect of mandating quality assurance under part 145. While half of the committee members regard requiring quality assurance as beneficial to repair stations that lack such programs, the remaining half believe that such a requirement would not achieve greater industry safety or quality for three reasons. First, many committee members believe that mandatory quality assurance would place a heavy burden on small repair stations and have a severe economic impact on this segment of the marketplace. Second, many committee members question whether the FAA has shown sufficient need for a mandatory quality assurance system. Many other industry representatives also express this view in comments. Third, most committee members have strong concerns about the effect disclosure of audit results might have on future FAA enforcement actions.

The committee members agree that quality assurance is important and that any repair station truly committed to quality and safety should have a quality assurance program. However, many on the committee believe that making quality assurance a regulatory control on repair stations fundamentally alters the nature of any quality assurance program. In most respects, quality assurance is self-imposed, driven by an inherent industrial motivation to produce quality results and compete effectively in the marketplace. By making quality assurance mandatory, some committee members believe that the line between regulatory control and business practice will become blurred. Without disputing the necessity of FAA safety regulations, members of the committee argue that quality assurance exists outside the limits of what can be regulated effectively.

REGULATORY BURDEN ON SMALL REPAIR STATIONS

Many committee members believe that the burden a mandatory system could place on small repair stations counsels against regulating quality assurance. Other industry representatives in comments to the FAA echo this concern. They fear that requiring a small repair station to conduct a formal internal audit would force that repair station to incur high costs. For example, a repair station with only one employee would have to require that employee to perform every aspect of the quality assurance program. Because most industry quality assurance programs require separating those who conduct the audit from those subject to the audit, most small repair stations would be forced to hire a third party to conduct audits. Several committee members express concern about the expense

of hiring an independent auditor. Further, the committee questions whether third party audits even should count toward meeting an FAA-mandated internal audit requirement.

Committee members did not argue that quality assurance itself poses a heavy financial burden on small repair stations. According to several committee members, most small repair stations engage in quality assurance, even if it only consists of a manager informally observing the performance of his employees as they go about their jobs. Committee members are concerned about the additional regulatory requirements the FAA is likely to impose on small repair stations under a mandatory quality assurance program. It bears repeating that all committee members regard quality assurance as valuable for repair stations. The concern lies with the possible requirements that the FAA might impose under a mandatory system.

In addition to concerns about the financial burden a mandatory quality assurance program might place on a small repair station, several committee members express concern about the time burden that would be placed on a small repair station. For example, a repair station with only one employee might not be able to commit to an audit that lasts for an extended period. Reserving even a few days for an audit would effectively eliminate a small repair station's ability to take in work during that same time, having serious consequences on that repair station's income.

Several committee members and the FAA suggest that repair station size be a factor in the FAA's requirements for a quality assurance program. Many committee members believe that having different requirements for large and small repair stations would help alleviate some of the concerns about overburdening small repair stations. However, some committee members note that placing more-extensive requirements on large repair stations might afford small repair stations a competitive advantage. Some on the committee believe that addressing these two concerns would result in a quality assurance system so limited in scope as to be worthless.

NEED FOR MANDATORY QUALITY ASSURANCE

Many committee members question whether the FAA has demonstrated sufficient need for a mandatory quality assurance system. A few committee members note that the United States has the best aviation safety record in the world. More important, the safety record surpasses those of European nations that have mandatory quality assurance programs under the Joint Aviation Requirements 145.65. The committee members argue, therefore, that the United States' safety record demonstrates that the U.S. aviation industry adequately addresses quality issues without the FAA's regulatory involvement.

Further, many committee members believe that the United States' safety record indicates that repair stations already are engaging in quality assurance without a regulatory mandate. They argue that the competitive nature of the aviation industry has made quality assurance essentially a necessity for most repair stations. For example, a repair station that wishes to compete seriously against a repair station that has a quality

assurance program must implement its own program to give potential customers a sense of comfort and also to ensure that its work is of comparable quality.

Therefore, committee members argue that the marketplace already is regulating the industry. One committee member states the issue very simply: A quality repair station probably already engages in effective quality assurance and therefore does not need to be regulated. Conversely, a repair station that is producing poor-quality work likely would implement its quality assurance program ineffectively. Therefore, requiring such a repair station to implement a quality assurance system would do little to improve the repair station's level of quality. Moreover, placing heavy regulatory burdens and the threat of enforcement actions on repair stations that already have quality assurance programs actually might serve as a deterrent to continue with a commitment to quality. Therefore, regulatory quality assurance might have no effect on poorly performing repair stations and a negative effect on those stations with rigorous quality assurance systems.

Committee members also express concern that allowing the FAA to regulate quality assurance would set aviation regulation down a "slippery slope," unnecessarily increasing regulatory control over the industry. For example, one committee member offers that an FAA mandate for a quality assurance system might lead to regulation of the specific procedures a repair station uses to ensure quality. Some committee members argue that quality assurance is part of a repair station's corporate culture. Allowing the FAA to mandate a quality assurance system might bring the Administration dangerously close to a repair station's business practices.

The committee adds that it is unclear how effective a mandatory quality assurance system would be. One committee member notes that merely having a quality assurance program does not ensure quality. The committee member argues that documentation, while offering a level of comfort to the FAA, often does not reflect the actual procedures of a repair station. A mandatory quality assurance system might serve only to mollify the FAA's safety concerns without really affecting quality or safety.

DISCLOSURE AND ENFORCEMENT ISSUES

Most committee members express strong concerns about requiring a repair station to reveal the results of internal audits to the FAA. The committee contends that when an audit reveals deficiencies, the FAA would use this information to take enforcement actions against the repair station. Therefore, repair stations may be reticent to reveal such deficiencies to the FAA.

All committee members and industry commenters agree that the purpose of a quality assurance system is to encourage a repair station to examine its policies and procedures periodically to make them better and safer. Many committee members and industry commenters express concern that mandating quality assurance would defeat this purpose and possibly cause a repair station to be less rigorous in its audit for fear of inadequacies that could result in enforcement action. Therefore, the committee believes that without

some measures to prevent the FAA from taking immediate enforcement action when it finds a deficiency, a mandatory quality assurance program would be wholly ineffective.

Committee members believe the FAA could address this concern by mandating a quality assurance program in which the repair station is not required to reveal details that might result in enforcement action. For example, a repair station could note general deficiencies that confirm it follows its quality assurance program.

Another solution the committee offers is that the FAA classify deficiencies uncovered during a quality assurance audit as major or minor. A repair station would have to reveal major deficiencies uncovered during an audit and would be required to engage in immediate corrective action or be subject to enforcement action. A major deficiency would pose an immediate safety threat, requiring a repair station to take immediate action to prevent the problem from presenting a safety hazard. Regardless of how the FAA addresses the issue, the committee believes that a quality assurance system repeatedly resulting in enforcement action would not improve quality in the industry and even might serve as a disincentive to uncover problems with a repair station's policies and procedures.

OPTIONS FOR A MANDATORY QUALITY ASSURANCE PROGRAM

The committee believes the FAA must address the issues identified in this report before any effective quality assurance program can be required of repair stations under part 145. All committee members agree that a mandatory quality assurance system will not achieve the results the FAA intends unless repair stations understand precisely what kind of quality assurance is required of them. The FAA could address this issue by providing clear guidance to repair stations.

Most committee members oppose a regulatory quality assurance system regardless of how the FAA implements it and regardless of how effective the guidance materials are. Therefore, the committee will only define what it believes are the basic elements of a quality assurance system.

BASIC ELEMENTS OF A MANDATORY QUALITY ASSURANCE PROGRAM

In reviewing industry quality assurance programs used, the committee members agree that there are four basic elements in any quality assurance system: auditing, root-cause analysis, corrective action and followup, and management review.

AUDITING

[The committee should provide a clear definition of “audit.”]

The committee finds that a fundamental requirement of any quality assurance system is auditing. Under a possible mandatory quality assurance system, a repair station would conduct audits of its operations to ensure that its manual complies with FAA regulations and that its operations conform to the requirements of its manual. The repair station's audit system methodology would require complete documentation of the audit. The committee agrees that a system of internal audits would include at least the following requirements.

First, a repair station would conduct scheduled audits on a periodic basis to ensure currency. The committee has not concluded how often a repair station should conduct audits; but the committee members agree that the repair station could divide its operations into sections, provided the repair station audits its entire operation within the applicable interval. For example, if the quality assurance system requires that a repair station audit its operations once every year, the repair station could audit different divisions of its operations separately, provided it audits its entire operations within the 1-year timeframe.

Second, a repair station would designate in its manual who can conduct audits. The committee believes that it might be necessary for some repair stations, especially smaller repair stations, to use third parties to complete audits. The committee has yet to reach a consensus on what third party audits would meet the requirements of a quality assurance system. The committee agrees that when an audit is performed internally, as most often

will be the case, the selected auditor should not audit the task for which he or she is responsible.

Third, a repair station should prepare for an audit prior to reviewing the repair station's operations. During this preparation, the repair station should review its manual alongside FAA regulations to ensure that the manual is in compliance. After reviewing all of the requirements of the repair station manual, an auditor would prepare a checklist of items to examine during the audit. During the audit, the individual designated by the repair station's manual would gather data, inspect the repair station's procedures and materials, and interview employees to determine whether the repair station's actual operations deviate from its manual requirements.

Fourth, the repair station would prepare a record of the audit. This record would document the audit process, note what aspects of the repair station's operations were audited, and indicate how the operations were audited. This documentation also would note the manner in which the auditor gathered the information, whether by examining the repair station's documents, by observing repair station employees' performance, or by interviewing repair station employees. If the auditor finds any deviations from the repair station manual, the auditor would document these findings and include objective evidence of the deviations in the audit record.

After the audit is completed and documented, a repair station would be required to complete the last three basic elements of the quality assurance system. The quality assurance system being discussed, however, also would require a repair station to complete the elements that follow whenever noncompliance with the repair station manual is found, whether during an audit or not, in accordance with §145.211. For example, if a repair station manager conducting a routine employee inspection notes that a mechanic is not following the procedures set forth in the repair station manual, this noncompliance would trigger the remaining basic elements of the quality assurance system even though the deviation was not observed during a formal audit.

ROOT CAUSE ANALYSIS

After a repair station completes an audit or discovers a deviation from repair station procedure, the repair station conducts a root-cause analysis. In this technical report, the committee defines root-cause analysis as a finding of a fundamental breakdown or failure within a system that, when resolved, prevents a recurrence of the problem. This analysis would include a requirement that the repair station then determine whether other products or systems in the repair station are impacted by the deviation. The committee agrees that the most important aspect of a quality assurance system would be timely analysis of the underlying cause of a deviation.

CORRECTIVE ACTION AND FOLLOW-UP

After a repair station discovers and documents a deviation and identifies its root cause, the repair station prepares a plan to remove the root cause. The repair station establishes immediate, short-term, and long-term actions to document implementation dates and identify responsible personnel. After the repair station implements a corrective action

plan, the repair station must validate that it took the necessary corrective action and has removed the root cause of the deviation. The committee agrees that it is important for a repair station to establish a feedback loop, that is, a system for ongoing evaluation of its policies and procedures. In addition, a repair station must take corrective action in a timely fashion. For deviations with possibly severe safety consequences, the FAA would require the repair station to take corrective action immediately or face enforcement action.

MANAGEMENT REVIEW

The committee agrees that a quality assurance system would hold the accountable manager responsible for overseeing the audit process and require him or her to review audit documentation to ensure the repair station personnel comply with regulatory requirements. The committee also agrees that the repair station manager may be required to conduct a trend analysis of past audit results to identify systemic problems with the repair station's procedures. The committee also believes the repair station manager must confirm that the repair station took corrective action that has removed the root cause of any deviations.

The committee notes this stage in the quality assurance process is also essential in ensuring that the repair station maintains a feedback loop. Especially at large repair stations, a manager might not have the chance to directly inspect or observe the performance of the employees. By maintaining an effective system of feedback and review, the manager has the resources to stay informed about the repair station's performance and to keep apprised of any trends that may emerge and demand a reassessment of that repair station's policies and procedures.

COST-BENEFIT ANALYSIS OF A MANDATORY QUALITY ASSURANCE PROGRAM

[This section to be included in final report]

VOLUNTARY QUALITY ASSURANCE PROGRAM

Several committee members recommend the FAA implement a voluntary quality assurance program. Under such a program, repair stations would comply voluntarily with FAA requirements for a quality assurance system. A repair station that complies with these standards would enjoy reduced inspection requirements, provided the repair station can demonstrate compliance. [The committee should clarify and expand this idea.]